Remarks

Claims 1-6 are pending. Claims 1 and 6 have been amended to specify that the network has at least two glass transition points. Support for the amendment is found, at least, on page 8, lines 21-23 and the Examples.

Rejection Under 35 U.S.C. § 102

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 93/17669 by Hubbell ("Hubbell"); U.S. Patent No. 5,854,382 to Loomis ("Loomis"); Sawhney *et al., Macromolecules*, 26(4), (1993) ("Sawhney"); and Kim *et al., Biomaterials*, 21, 259-265 (2000) ("Kim"). Applicants respectfully traverse this rejection.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 480 US 947 (1987); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 U.S.P.Q.2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, Id.:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 U.S.P.Q . 649, 653 (Fed. Cir. 1986).

Analysis

Claims 1 and 6, as amended, are directed to an amorphous shape memory polymeric network comprising a crosslinked ABA triblock dimethacrylate macromonomer, wherein the macromonomer comprises blocks derived from polyesters and polyethers, and wherein the network has at least two glass transition points, and methods of making thereof. A shape

memory polymer is defined as a material which possesses at least two shapes in memory: a permanent shape and at least one temporary shape (page 1, lines 12-13). The material can be converted from its permanent shape to a temporary shape and back again by applying an external stimulus, such as a change in temperature (page 1, lines 14-15). The claimed compositions contain at least two glass transition points: the formation of covalent crosslinks, which establishes the permanent shape of the material and the glass transition point of the triggering segments, which establishes at least one temporary shape.

a. Sawhney et al., Macromolecules, 26(4), (1993) ("Sawhney")

Sawhney describes bioerodible hydrogels having a poly(ethylene glycol) central block with oligomers of α-hydroxy acids, such as oligo(*dl*-lactic acid) or oligo(glycolic acid) and terminated with acrylate groups (abstract). Sawhney does not disclose amorphous shape memory polymeric networks, wherein the networks have at least two glass transition points. The hydrogels described in Sawhney do not have a permanent shape and at least one temporary shape. Hydrogels typically exhibit only a single glass transition temperature (see page 585, Figure 4, which describes the single glass transition temperature observed for hydrogels formed by photocrosslinking poly(ethylene glycol-co-poly(α-hydroxy acid) macromers). In order to for a reference to anticipate, it must disclose, expressly or inherently, each and every element of the claim. Sawhney does not disclose, expressly or inherently, amorphous polymeric shape memory networks, wherein the networks have at least two glass transition points. Accordingly, claims 1-6 are novel over Sawhney.

b. WO 93/17669 to Hubbell ("Hubbell")

Hubbell describes hydrogels of polymerized and crosslinked macromers containing hydrophilic oligomers having biodegradable monomeric or oligomeric extensions, wherein the biodegradable extensions are terminated on free ends with end cap monomers or oligomers capable of polymerization and crosslinking (abstract). Hubbell does not disclose amorphous shape memory polymeric networks, wherein the networks have at least two glass transition points. The hydrogels described in Hubbell do not have a permanent shape and at least one temporary shape. Hydrogels typically exhibit only a single glass transition temperature (see Sawhney, page 585, Figure 4, which describes the single glass transition temperature observed for hydrogels formed by photocrosslinking poly(ethylene glycol-co-poly(α-hydroxy acid) macromers). In order to for a reference to anticipate, it must disclose, expressly or inherently, each and every element of the claim. Hubbell does not disclose, expressly or inherently, amorphous polymeric shape memory networks, wherein the networks have at least two transition points. Accordingly, claims 1-6 are novel over Hubbell.

c. Kim et al., Biomaterials, 21, 259-265 (2000) ("Kim")

Kim describes biodegradable hydrogels formed from poly(ether-ester) networks prepared by UV photopolymerization (abstract). Kim does not disclose amorphous shape memory polymeric networks, wherein the networks have at least two glass transition points. The hydrogels described in Kim do not have a permanent shape and at least one temporary shape. Hydrogels typically exhibit only a single glass transition temperature (see Sawhney, page 585,

Figure 4, which describes the single glass transition temperature observed for hydrogels formed by photocrosslinking poly(ethylene glycol-co-poly(α-hydroxy acid) macromers). In order to for a reference to anticipate, it must disclose, expressly or inherently, each and every element of the claim. Kim does not disclose, expressly or inherently, amorphous polymeric shape memory networks, wherein the networks have at least two glass transition points. Accordingly, claims 1-6 are novel over Kim.

d. U.S. Patent No. 5,854,382 to Loomis

Loomis describes crosslinked hydrogels formed from water-insoluble copolymers (abstract). The copolymers contain a bioresorbable region, a hydrophilic region, and at least two crosslinkable functional groups per polymer chain (abstract). Loomis does not disclose amorphous shape memory polymeric networks, wherein the networks have at least two glass transition points. The hydrogels described in Loomis do not have a permanent shape and at least one temporary shape. Hydrogels typically exhibit only a single glass transition temperature (see Sawhney, page 585, Figure 4, which describes the single glass transition temperature observed for hydrogels formed by photocrosslinking poly(ethylene glycol-co-poly(α-hydroxy acid) macromers). In order to for a reference to anticipate, it must disclose, expressly or inherently, each and every element of the claim. Loomis does not disclose, expressly or inherently, amorphous polymeric shape memory networks, wherein the networks have at least two glass transition points. Accordingly, claims 1-6 are novel over Loomis.

Allowance of claims 1-6, as amended, is respectfully solicited.

Respectfully submitted,

/Michael Terapane/
Michael Terapane, Ph.D.
Reg. No. 31,284

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PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2155
(404) 879-2160 (Facsimile)